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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/028,050	12/20/2001	Nikolaos V. Tsekos	600.466US2	4434

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EXAMINER

SHAW, SHAWNA JEANNINE

ART UNIT PAPER NUMBER

3737

DATE MAILED: 03/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/028,050	TSEKOS
	Examiner	Art Unit
	Shawna J. Shaw	3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2001 and 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 26-56 is/are pending in the application.
- 4a) Of the above claim(s) 1-13 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>5</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to an MRI-guided method for performing an invasive procedure, classified in class 600, subclass 411.
- II. Claims 27-56, drawn to a stereotactic apparatus for inserting a probe into a region, classified in class 606, subclass 130.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used with imaging modalities other than MRI, such as x-ray, and is not limited to imaging a breast.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with David W. Black on 3/3/04 a provisional election was made without traverse to prosecute the invention of Group II, claims 27-56. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-13 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is vague and indefinite in that the scope cannot be clearly delineated. More particularly, it is unclear whether the entire system, or merely a portion thereof (e.g., the compression plates), is comprised of MRI compatible material. If applicant intends the entire system to be fabricated of MRI compatible material, the claim should be amended to clearly state this.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27-43, 48 and 51-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Siczek et al.

Regarding claims 27-37, 40-43, 48, 51-54 and 56, Siczek et al. teaches a mammographic biopsy apparatus including first and second compression plates (128, 126), compression adjuster (col. 12 line 67 – col. 13 line 4), stage/platform (130), and probe guide (132). Siczek et al. further discloses wherein: the linear movement of the compression plates; the vertical and rotational position of stage (130) with respect to supporting surface (120); and the angle and depth of the probe guide (132), are controlled via conventional motorized mechanisms in a remote fashion using a control handle or footswitch. See col. 11 lines 31-49 and col. 12 line 62 – col. 13 line 19. Regarding claims 38 and 39, Siczek et al. discloses wherein support surface (120) is adapted to rotate along an axis parallel to the spine of a patient (see fig. 8 and col. 13 lines 36-47). Further regarding claim 55, it appears from figure 7 that the probe (134) is passed through compression plate (128).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siczek et al. in view of Russell et al.

Regarding claim 44, Siczek et al. differs from the claimed invention in that a window is not specifically addressed. Russell et al. teaches performing a breast biopsy through a compression plate having a window (26). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use a first compression plate having a window as taught by Russell et al. in the invention as taught by Siczek et al. to provide less restricted access to the target region and to avoid contamination of the compression plate.

Claims 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siczek et al. in view of Russell et al. and further in view of Chakeres.

Regarding claims 45-47, Siczek et al. and Russell et al. differ from the claimed invention in that a permeable or mylar cover is not specifically addressed. Chakeres teaches advancing a probe through an imager compatible covering (composed of e.g., mylar) having markings thereon. See col. 15 lines 45-48 and col. 16 lines 42-49. It would have been obvious at the time the invention was made to cover the window of Siczek et al. in view of Russell et al. with a stereotactic covering as taught by Chakeres to provide more accurate needle guidance while maintaining a sterile procedure.

Claims 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siczek et al. in view of Panetta et al.

Regarding claims 49 and 50, Siczek et al. differs from the claimed invention in that the composition of the components is not addressed explicitly. Panetta et al.

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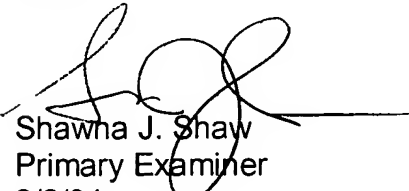
discloses a mammographic system having plastic components (see elements 30, 45 and 65). It would have been obvious at the time the invention was made to a person of ordinary skill in the art to use plastic materials in the biopsy system of Siczek et al. as taught by Panetta et al. as a cheaper, well known expedient in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawna J. Shaw whose telephone number is (703) 308-2985. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.


Shawna J. Shaw
Primary Examiner
3/8/04